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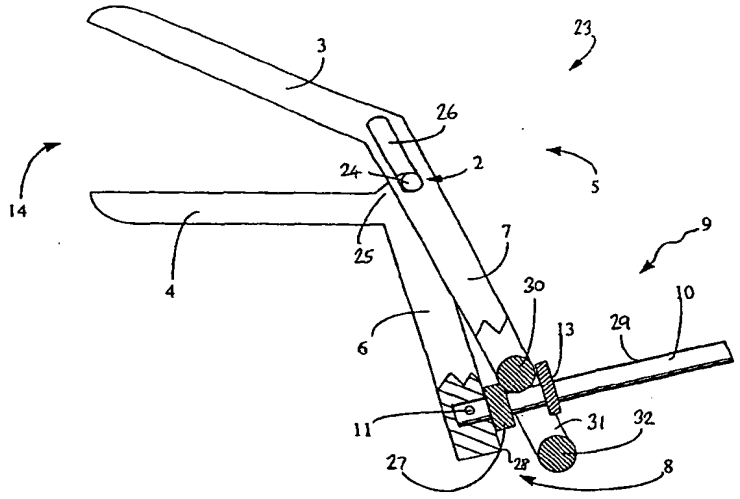

(57) Abstract

A speculum (23) comprises a first blade (4), within which are optionally mounted a pair of side blades, associated with a forward operating lever (6), and a second blade (3) associated with a rearward operating lever (7) that is connected by a pivot (2) to the forward operating lever. The pivot is a floating pivot permitting relative translational movement between the operating levers. The operating levers are also connected by a ramp (10), and a ramp follower (30), the ramp being opposed to the pivot so that the pivotally connected operating levers, and the ramp define a triangle. During relative pivotal movement of the operating levers towards one another, the ramp follower moves up the ramp towards the pivot, and this movement of the ramp follower up the ramp causes translational movement at the floating pivot that widens the proximal aperture between the blades. In addition, the side blades can be employed selectively to improve visual, and physical access to the cavity in which the speculum is used.

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TITLE: SPECULUM

This invention relates to a speculum. Preferred embodiments of the invention relate to a speculum for use in gynaecological examination of the vaginal canal and cervix, and in related procedures such as investigation and surgery.

The use of specula in gynaecological examinations dates back to ancient times. In fact Hippocrates himself is reputed to have made use of specula, and several versions were unearthed at Pompeii. Use of specula in the United Kingdom was frowned upon during the Victorian era and gynaecological examinations were performed from a distance without physically touching the patient.

In later years, physical examinations did take place but even then the patient remained fully clothed. Eventually patients would undress for examinations but inspection of the vaginal canal and cervix remained impossible until the invention of the bivalve speculum. This instrument is inserted into the vagina and opened to push back the vaginal walls and labia, thereby providing access to the vaginal canal and cervix for viewing and for the performance of any other procedures that may be necessary, including surgery.

Bivalve specula include a co-operating pair of curved, hollow, tapering blades. The blades are joined near their proximal ends by a hinge. The hinge enables the blades to be flexed apart at their distal ends to increase the diameter of the vaginal canal, allowing examination of the inner vaginal walls and cervix through a proximal viewing aperture defined by the co-operating proximal end portions of the blades. The proximal aperture is not just for viewing but also defines a path to admit instruments for inspection, investigation or surgery, such as a spatula used for smear testing or a cone biopsy instrument for treating cervical lesions. Accordingly, access through the proximal aperture is not just visual but physical.

Most typical modern specula share the same features, namely at least two blades, often resembling a duck's bill, with a handle depending from the proximal end of the blades for the physician to hold. Most often the handle comprises at least one operating lever that can be moved to open or close the blades. Most specula also have a locking mechanism for locking the blades in position against vaginal contraction once opened to a desired extent.

Modern specula can be made from any of a variety of different materials. Surgical

stainless steel is most common but disposable plastic specula are also available. Some are adapted to take suction tubes for smoke evacuation following electrosurgical treatment. Others may be adapted to allow fluid to drain easily, or to support instruments used for inspection, investigation or surgery.

Over the years, specula have been adapted and redesigned, and new types invented, to suit different requirements. The result is that several different types of specula are used in medicine today. In Europe, fixed-hinged bivalve specula, most notably Cuscoe's speculum, are in widespread use. Reference is made in this respect to Figures 1 and 2, which show Cuscoe's speculum 1 in schematic pan-sectioned side view to illustrate its operation. A fixed hinge 2 joins the blades 3, 4 at the proximal end 5, about which the blades 3, 4 (shown closed in Figure 1) can be flared apart as shown in Figure 2. This causes the blades 3, 4 to dilate the vaginal canal (not shown) in use.

Cuscoe's speculum 1 is operated using two operating levers 6, 7 depending from the proximal end 5, the levers 6, 7 being disposed one behind the other to act together as a handle generally indicated as 8. The distal or forward operating lever 6 depends distally from the lower blade 4 and the proximal or rearward operating lever 7 depends proximally from the upper blade 3. Squeezing the operating levers 6, 7 together about the hinge 2 flares apart the blades 3, 4.

A locking mechanism generally indicated as 9 prevents the blades 3, 4 from closing due to the inherent inward pressure exerted by stretched vaginal walls. This mechanism 9 consists of a threaded rod 10 joined by a pivot 11 to the forward operating lever 6. The rod 10 passes through a slot 12 in the rearward operating lever 7. A nut 13 in threaded engagement with the rod 10 can be tightened against the rearward operating lever 7, to which end the nut 13 cannot pass through the slot 12. Inward pressure from the vaginal walls tends to cause the blades 3, 4 to close and thus the operating levers 6, 7 to separate. Tightening the nut 13 against the rearward operating lever 7 as shown in Figure 2 prevents further separation of the operating levers 6, 7 and thus closing of the blades 3, 4.

Since the upper and lower blades 3, 4 are joined directly by the hinge 2, the blades 3, 4 cannot be separated at their proximal ends 5 in the region of the hinge 2. Due to the flaring angle of the blades 3, 4, dilation of the vaginal canal is greatest at the distal end 14 of the speculum and decreases towards the proximal end 5. Thus although the vaginal canal may be sufficiently dilated around the cervix for

examination, the vaginal canal nearer the labia, especially at the vaginal, opening or introitus, may be less dilated and still obstruct the physician's view and access.

Unfortunately, the fixed hinge arrangement of Cuscoe's speculum means that the proximal aperture through which the operating physician must work in use is fixed and cannot be increased in size to expand the introitus. These disadvantages of Cuscoe's speculum are shared by other specula that have their blades joined directly together in corresponding fixed-hinge fashion.

Accordingly, mobile-hinged bivalve specula have become popular. Graves' speculum is the best-known example of this type and is widely used in North America. This speculum is illustrated in schematic part-sectioned side view in Figures 3 and 4 and, in comparison with Figures 1 and 2, like numerals are used for like parts.

Unlike Cuscoe's speculum, Graves' speculum 15 does not have the upper and lower blades 3, 4 joined directly together. This provides a means for increasing the size of the proximal aperture when desired.

The handle 8 of Graves' speculum 15 comprises one operating lever, namely the forward operating lever 6, and a Y-shaped carriage 16 slidably attached behind the forward operating lever 6. As in Cuscoe's speculum, the forward operating lever 6 depends from the lower blade 4. However, in this instance the forward operating lever 6 is disposed at an angle of around 90° to the lower blade 4 rather than being acutely angled forward or distally as in Cuscoe's speculum.

The upper portion of the carriage 16 defines arms 17 (only one arm 17 is shown in the side view of Figures 3 and 4) that splay apart from a leg 18 of the carriage 16 to define a proximal aperture and that support the upper blade 3 by means of a hinge 2. Another, rearward operating lever 7, depends rearwardly or proximally from the proximal end of the upper blade 3 and is situated to one side of the viewing aperture, where it can be actuated by the physician's thumb. Pressing the rearward operating lever 7 distally, towards the carriage 16, flares the blades 3, 4 apart.

As in Cuscoe's speculum, the blades 3, 4 of Graves' speculum 15 can be held in position against inward pressure from the vaginal walls by using a locking mechanism generally indicated as 9 to lock the flared blades 3, 4. To this end, a threaded rod 10 hingeably attached to the carriage 16 passes through a slot (in this instance, not shown) in the rearward operating lever 7. The pressure of the vaginal

walls closing the blades 3, 4 tends to move the rearward operating lever 7 away from the carriage 16. Tightening a nut 13 in threaded engagement with the rod 10 against the rearward operating lever 7 prevents the lever 7 being moved away from the carriage 16 and in doing so prevents the blades 3, 4 closing.

As these aspects of Graves' speculum 15 are akin to Cuscoe's speculum, the blades 3, 4 are shown closed in both Figures 3 and 4, it being understood that the blades 3, 4 can be flared apart when desired in the manner of Cuscoe's speculum 1 illustrated in Figure 2. Instead, the key feature of Graves' speculum is that the upper blade 3 and carriage 16 arc movable in relation to thc lower blade 4 and forward operating lever 6. This feature, embodied in an adjustment mechanism 19, will now be described in more detail.

A pin 20 passes through a slot 21 extending along the leg 18 of the carriage 16 and is fixed to the forward operating lever 6, the arrangement being such that the pin 20 can slide back and forth in the slot 21 as the forward operating lever 6 and the leg 18 of the carriage 16 slide relative to one another. This enables the upper blade 3 to be moved away from the lower blade 4 without any flaring between the blades 3, 4, as shown in Figure 4. The arms 17 defined by the Y shape of the carriage 16 define the width of a proximal aperture as mentioned above and when the blades 3, 4 are separated in this way, the proximal aperture increases in depth.

The pin 20 is threaded so that a nut 22 in threaded engagement with the pin 20 can be tightened against the leg 18 of the carriage 16 to clamp the carriage 16 and forward operating lever 6 together and so prevent their sliding movement relative to one another. The locked carriage 16 stops the proximal ends 5 of the blades 3, 4 from being pushed together under vaginal pressure in use, which otherwise would reduce the proximal aperture.

It will be noted that the locking mechanism 9 and the adjustment mechanism 19 of Graves' speculum 15 are independent: locking flaring 'of the blades 3, 4 does not prevent their proximal separation by sliding the carriage 16 relative to the forward operating lever 6, and locking the carriage 16 relative to the forward operating lever 6 does not prevent flaring of the blades 3, 4.

Unfortunately, the design of Graves' speculum 15 is such that the flaring, adjusting and locking operations involve separate steps or actions and are difficult or impossible to perform one-handed. Accordingly, although more adaptable than Cuscoe's speculum 1, Graves' speculum 15 is more complicated and time-

consuming to use. First, for example, the upper blade 3 may have to be flared away from the lower blade 4 and locked in position. Then the proximal separation between the blades 3, 4 may have to be adjusted by moving the carriage 16, whereupon the carriage 16 must be locked in position relative to the forward operating lever 6. Further, it may be that in proximally separating the blades 3, 4, a further adjustment of their flaring angle has to be made.

This protracted routine is not desirable for 'a patient who is probably already uncomfortable with the idea of undergoing such an intimate procedure, especially when one considers that this all occurs before any steps of inspection, investigation or surgery that may be necessary.

Graves' speculum 15 has a further problem that is shared with Cuscoe's speculum 1. This is that when the handle 8 or part thereof is at an acute angle, or at most at a right angle, to the blades 3, 4, the physician's hands and especially fingers are inevitably brought into close proximity to, if not into contact with, the patient's genitalia, buttocks and anus during a gynaecological procedure. This situation is potentially distressing not only for the patient but also for the physician, who would not wish to be accused of any impropriety.

In summary, therefore, the specula presently available suffer from being inflexible and awkward to adjust, or in the case of Cuscoe's speculum, are not truly adjustable at all. Graves' speculum is adjustable but suffers from being too complex and difficult to manipulate. A readily-adjustable speculum is therefore desirable.

Whilst the principal object of this invention is to solve the problems mentioned above, the Inventor is aware of a further disadvantage of bivalve specula which is that, occasionally, very lax vaginal walls can prolapse and protrude inwardly between the open blades of the speculum in use, thus obstructing the physician's view and access. This may make it impossible properly to expose the cervix for procedures such as inspection, investigation such as smear-taking and treatment such as electrosurgery. Embodiments of the invention that will be described hereinafter have supplementary blades to deal with this thankfully uncommon situation.

Against this background, the present invention contemplates a speculum comprising co-operating blades defining a proximal aperture, each blade being associated with a respective operating lever such that relative movement of the operating levers causes relative movement of thc blades, wherein a mechanism

operable by said relative movement of the operating levers causes the proximal aperture to vary.

The speculum of the invention can therefore be configured so that squeezing together the operating levers will automatically cause the proximal aperture to widen. This inherently one-handed squeezing action is intuitively familiar to physicians used to instruments such as Cuscoe's and Graves' specula and, in any event, is necessary to flare or splay apart the distal ends of the blades. So, this single action achieves an advantageous compound movement of the blades that, previously, either was not possible or involved more than one action or more than one hand.

In preferred embodiments, the mechanism includes a ramp along which a ramp follower can move, preferably though not essentially by sliding, during said relative movement of the operating levers. In this case, relative movement of the ramp follower along the ramp causes the desired variation of the proximal aperture.

To reduce friction in sliding arrangements, the ramp follower is advantageously shaped to define a line of contact with the ramp, for example being cylindrically curved about an axis transverse to the direction of movement along the ramp. The line of contact is then transverse to the direction of movement along the ramp. The ramp follower can be as simple as a bearing formation on one of the operating levers, such as a cross-bar of circular cross-section as will be described hereinafter.

To prevent relative movement of the operating levers as the blades are subject to inward pressure in use, a first locking member such as a nut may be movable with respect to the ramp.

The ramp is preferably attached to or part of one of the operating levers and the ramp follower is attached to or part of the other of the operating levers. More preferably, the ramp is movably attached to an operating lever, for example by a pivot. The ramp should then be lockable to prevent movement relative to that operating lever, for example by a second locking member such as a nut that is movable with respect to the ramp to lock the ramp relative to the operating lever.

In preferred embodiments, the ramp is defined by a rod along which the first and/or second locking members can be moved. In a simple and elegant arrangement, the rod is threaded and the first and second locking members are nuts in threaded engagement with the rod. However, in this case, a bearing surface of the rod may be non-threaded to facilitate sliding movement of the ramp follower with respect to the ramp defined by the rod.

To minimise the extent to which the physician's hands touch the patient in use of the speculum, it is highly advantageous if the operating levers are obtusely angled in a proximal direction with reference to the blades. Also, for the benefit of physicians used to using traditional instruments such as Cuscoe's and Graves' specula, the operating levers are preferably disposed one behind another as forward and rearward operating levers. Then, where the operating levers are obtusely angled as aforesaid, the rearward operating lever is suitably oriented at a greater obtuse angle to the blades than the forward operating lever.

The problem of lax vaginal walls prolapsing between open speculum blades may be solved in arrangements where the blades are upper and lower blades that co-operate when closed to define a hollow body and supplementary blade means are situated within the body, wherein the supplementary blade means comprise side blades that open laterally from within the body when the upper and lower blades are opened. In the embodiment that will be described, a drive means is associated with at least one of the operating levers to actuate the supplementary blade means upon relative movement of the operating levers. However, as this facility is needed only occasionally, it is preferred that the drive means is selectable to prevent relative movement of the operating levers from actuating the supplementary blade means.

The drive means suitably comprises a drive member, for example in the form of a flap, attached to or part of an operating lever that bears against proximal ends of the side blades when the upper and lower blades are opened and causes the side blades to move distally against an actuating member such as a post that causes the side blades to splay apart. To make the drive means selectable, the flap can be pivotally mounted so that it can be swung out of possible engagement with the supplementary blade means when that facility is not required.

For optimally compact stowage of the side blades when they are not in use, it is preferred that the side blades are movably attached to the lower blade by a floating mount such as a pin that permits the side blades to lift out of the interior of the lower blade as they splay apart.

The preferred embodiments contemplate a speculum whose blades are joined for cooperating relative movement by a floating hinge or pivot. The part played by the floating hinge or pivot will be described in detail in the specific description with reference to Figures 5 to 7. However, it is appropriate: here to summarise this aspect in conceptual 'picture claim' terms within the embracing inventive concept.

Thus expressed, the invention resides in a speculum comprising first and second blades that co-operate to define a proximal aperture, the first blade being associated with a first operating lever and the second blade being associated with a second operating lever that is connected by a pivot to the first operating lever such that relative pivotal movement of the operating levers towards one another causes the blades to move apart, wherein the pivot is a floating pivot permitting relative translational movement between the operating levers to vary the proximal aperture and wherein the operating levers are also connected by a ramp associated with the first operating lever and a ramp follower associated with the second operating lever, the ramp being opposed to the pivot so that the pivotally-connected operating levers and the ramp define the three sides of a triangle, the arrangement being such that during relative pivotal movement of the operating levers towards one another, the ramp follower moves up the ramp towards the pivot, this movement of the ramp follower up the ramp causing translational movement at the floating pivot of the second operating lever, which translational movement widens the proximal aperture. Movement of this operating lever may thus have a translational component and a pivotal component.

The invention contemplates means whereby the ramp or the ramp follower can be adjusted so as not to come into contact with one another during said relative pivotal movement of the operating levers towards one another. As aforesaid, the ramp may be pivotally movable in relation to the first operating lever, and locking means may be provided to hold the ramp in fixed angular relation to that operating lever during said relative pivotal movement of the operating levers towards one another.

Inventive matter also resides in a speculum having supplementary blade means irrespective of whether or not means are provided for varying the proximal aperture. Hence, the invention extends to a speculum having upper and lower blades that co-operate when closed to define a hollow body and supplementary blade means situated within the body, the supplementary blade means comprising side blades that open laterally from within the body when the upper and lower' blades are opened. Preferred optional features of, and relating to, the supplementary blade means are set out above and in the specific description.

The speculum of the invention is preferably a bivalve speculum in the sense of having two primary blades, and although supplementary blades such as side blades can be added to the primary blades, these can be regarded as being of a secondary

nature and hence not altering the bivalve character of the speculum.

Detailed reference has already been made to the prior art drawings Figures 1 to 4. In order that the present invention can be more readily understood, reference will now be made, by way of example only, to the accompanying further drawings in which:

Figure 5 is a perspective view from the proximal end and one side of a speculum in accordance with a preferred embodiment of the invention, showing various novel features and adaptations associated with the operating levers and the hinge between the blades;

Figure 6 is a simplified schematic side view of the speculum of Figure 5 showing how the locking mechanism is adapted to define a ramp, in which drawing the blades, and the proximal aperture that the blades define, are in a closed position;

Figure 7 is a simplified schematic side view corresponding to Figure 6, but showing the blades and the proximal aperture in a fully opened position by virtue of the ramp;

Figure 8 is a simplified schematic plan view of a lower blade of the speculum of Figures 5 to 7, a pair of side blades stowed within the lower blade in a closed, inoperative position; and

Figure 9 is a simplified schematic plan view corresponding to Figure 8, but showing the side blades fully splayed apart and deployed from within the lower blade into an operative position effective to hold back lax vaginal side walls.

Referring firstly to Figure 5, 6 and 7 of the drawings, a speculum 23 in accordance with a preferred embodiment of the invention is broadly akin to Cuscoe's speculum illustrated in Figures 1 and 2 and so, again, like numerals are used for like parts. Thus, a hinge 2 joins the blades 3, 4 at the proximal end 5. Two operating levers 6, 7 located at the proximal end 5 are disposed one behind the other to define a handle generally indicated as 8, the forward operating lever 6 being associated with the lower blade 4 and the rearward operating lever 7 being associated with the upper blade 3 so that squeezing the operating levers 6, 7 together about the hinge 2 flares apart the blades 3, 4.

To illustrate the size of the speculum 23, the blades 3, 4 are each about 15 cm long and the operating levers 6, 7 are each about 10 cm long. The instrument is typically fashioned of stainless steel. Whilst the operating levers 6, 7 are shown fixed to the respective blades for simplicity, it is equally possible for the operating levers 6,

7 to be mounted to the blades by hinges at any point along their length. Such a facility is well known in the speculum art and allows the handles to be folded away for compact storage.

As in Cuscoe's speculum of Figures 1 and 2, a locking mechanism generally indicated as 9 prevents the blades 3, 4 from closing under inward pressure exerted by the vaginal walls. This locking mechanism 9 consists of a threaded rod 10 joined by a pivot 11 to the forward operating lever 6 and a nut 13 in threaded engagement with the rod 10 (the nut 13 shown in Figure 5 is a wing nut) that can be tightened against the rearward operating lever 7 to prevent closing of the blades 3, 4. The pivot 11 is suitably constructed by inserting a pivot end of the rod 10 into a matching recess in the forward operating lever 6 and then passing a pivot pin through aligned transverse holes in both the forward operating lever 6 and the pivot end of the rod 10.

However, it will be apparent from Figure 5 that the speculum 23 of the invention has several features that differ from Cuscoe's speculum. Most obviously at first sight, the operating levers 6, 7 are both angled backwards or proximally at an obtuse angle to the respective blades 3, 4, the obtuse angle of the rearward operating lever 7 being greater than the obtuse angle of the forward operating lever 6. This minimises the risk of the physician's hands touching the patient's genitalia, buttocks and anus during a gynaecological procedure, in contrast to both Cuscoe's speculum and Graves' speculum whose handles 8 depend at an acute distal angle, or at most at a right angle, from the blades 3, 4.

However, perhaps the major novel aspect of the speculum 23 lies in its facility for one-handed, one-action essentially automatic adjustment of the proximal spacing between the blades 3, 4, in which respect reference will now be made mainly to the simplified side views of Figures 6 and 7.

It will be noted from Figures 5 to 7 that the hinge 2 is a floating hinge or pivot in which a pair of hinge pins 24 project laterally from proximal extensions 25 of the lower blade 4 so that one hinge pin 24 is disposed on each side of the viewing aperture at the proximal end 5. For that reason, only one hinge pin 24 is visible in the views of

Figures 5, 6 and 7, it being understood that a corresponding hinge pin 24 is out of sight on the other side of the speculum 23. Each hinge pin 24 is received within a slot 26 that extends along the rearward operating lever 7 associated with the upper

jaw 3, so that relative translational movement can take place between the hinge pins 24 and their respective slots 26 within a range defined by the length of the slots 26.

In the illustrated embodiment, the slots 26 are about 2 cm in length. The hinge pins 24 can be integral with the extensions 25 from which they project, or they can be separate components attached to the extensions 25.

Moving down to the locking mechanism 9 and its relationship with the rear operating lever 7, these components are adapted in various ways compared: with Cuscoe's speculum.

Firstly, means are provided for locking the threaded rod 10 against movement about the pivot 11, in the form of a lock nut 27 in threaded engagement with the rod 10. The lock nut 27 can be advanced along the rod 10 to bear against the rear or proximal surface 28 of the forward operating lever 6, thereby locking the rod 10 at 90° to the forward operating lever 6. This mode of use is illustrated in Figures 6 and 7.

Secondly, the rod 10 has a flat, non-threaded bearing surface 29 facing the hinge 2. This bearing surface 29 is most conveniently created by grinding flat a strip-like upper portion of the thread on the side of the rod 10 that faces the hinge 2.

Thirdly, the free end of the rearward operating lever 7 is generally U-shaped and the arms of the U are linked by a cross-bar 30 of circular cross-section and cylindrical shape. An aperture 31 is defined between the cross-bar 30 and the arched extremity 32 of the U-shaped end of the rearward operating lever 7, and the rod I0 extends through the aperture 31. Thus, as best shown in Figures 6 and 7, the cross-bar 30 slides along the beating surface 29 of the rod 10 when the rod 10 is locked at 90° to the forward operating lever 6 and the operating levers 6, 7 are squeezed together as in Figure 7. It will be noted that the cylindrical shape of the cross-bar 30 presents a transverse line of contact to the bearing surface 29 irrespective of the relative orientation of the operating levers 6, 7, thus ensuring low friction throughout the range of relative movement between the operating levers 6, 7.

During this squeezing movement, the rod 10 may be regarded as a ramp because it lifts the cross-bar 30 and hence the rearward operating lever 7 as that lever approaches the forward operating lever 6. The geometric conflict that would otherwise occur is accommodated and resolved by the floating hinge 2, specifically as relative movement of the hinge pins 24 within their respective slots 26 results in

the hinge pins 24 moving toward the lower end (as illustrated) of the slots 26. It would equally be true to say that the slots 26 move over the hinge pins 24, as the movement in question is relative rather than with respect to any fixed datum.

This movement has the effect of automatically widening the proximal spacing between the blades 3, 4 in the region of the hinge 2, and hence the proximal aperture, in the same one-handed movement that causes the blades 3, 4 to flare apart about the hinge 2. The simplicity of this action can be contrasted with the complexity of achieving a corresponding adjustment of Graves' speculum. Conversely, the invention adds a useful facility to Cuscoe's speculum without complicating its operation, which could otherwise alienate physicians familiar with the use of Cuscoe's speculum.

As with Cuscoe's speculum and as shown in Figure 7, the nut 13 can be advanced along the rod 10 when the operating levers 6, 7 are squeezed together until the nut 13 bears against the rear surface of the rearward operating lever 7, or its cross-bar 30 as shown in Figure 7, and so prevents the blades 3, 4 moving towards each other under vaginal pressure. The speculum 23 of the invention can also be used in the same manner as Cuscoe's speculum, simply by slackening off the lock nut 27 to allow pivotal movement between the rod 10 and the forward operating lever 6. In that mode of operation, the rod 10 can pivot up and down within the aperture 31 defined between the cross-bar 30 and the arched extremity 32 of the U-shaped end of the rearward operating lever 7. This pivoting movement of the rod 10 will usually be sufficient to resolve any geometric conflict during a squeezing action without involving the floating hinge 2 which, in use under inward vaginal pressure, will tend to adopt the proximally closed configuration shown in Figure 6. Indeed, the rod 10 can pivot to the extent that the cross-bar 30 of the rearward operating lever 7 no longer needs to bear against the bearing surface 29 of the rod 10.

It will be apparent that the lock nut 27 can be slackened off to varying degrees and that the more it is slackened off by being withdrawn along the rod 10, the greater the possible range of pivotal movement of the rod 10. The limits of pivotal movement are defined where the lock nut 27 bears against the rear surface 28 of the forward operating lever 6. Accordingly, the rod 10 need not be locked at precisely 90° to the forward operating lever 6: for example, there may be instances in which an obtuse angle to the forward operating lever 6 is advantageous. In that case, the cross-bar

30 of the rearward operating lever 7 may be kept clear of the rod 10 during initial squeezing movement of the rearward operating lever 7 towards the forward operating lever 6, thus exerting no expanding force on the floating hinge 2. Only at the end of that squeezing movement does the ramp surface 29 defined by the rod 10 come into play to bear against the cross-bar 30 of the rearward operating lever 7 and hence cause proximal separation of the blades 3, 4 via the floating hinge 2. Thus, the extent of proximal separation can be controlled by the angle of the rod 10 to the forward operating lever 6.

Returning to Figure 5 and with reference now also to Figures 8 and 9, the speculum 23 illustrated in Figure 5 has further optional features associated with the lower blade 4 and the rearward operating lever 7. These features include selectable drive means associated with the rearward operating lever 7 that interact with supplementary blade means concealed within the closed blades 3, 4. The supplementary blade means are provided to deal with the aforementioned problem of slack vaginal walls prolapsing inwardly between the primary (upper and lower) blades 3, 4 and hence potentially blocking or restricting the physician's view.

Specifically, the selectable drive means comprises a flat, oblong flap 33 attached to the rearward operating lever 7 by a pair of opposed lugs 34 that each project from a respective long side of the flap 33 and divide the flap 33 transversely into major and minor portions in a ratio of approximately 1/3: 2/3. The lugs 34 are pivotally received in respective holes 35 provided in the arms of the U-shaped rearward operating lever 7, whereby the flap 33 can be pivoted about the lugs 34 with respect to the lever 7. Stops'36 projecting laterally from an end of the flap 33 prevent continued pivoting when the stops 36 bear against the arms of the U-shaped rearward operating lever 7 as illustrated in Figure 5.

In the mode shown in Figure 5, the flap 33 is oriented so that, as illustrated, its major portion lies above the pivot axis defined by the lugs 34. In this mode, the major portion of the flap 33 is positioned to engage and actuate the supplementary blade means concealed within the closed blades 3, 4.

Referring now specifically to Figures 8 and 9 of the drawings, it will be seen that the hollow lower blade 4 contains and supports the supplementary blade means which comprises first and second side blades 37 that can be splayed apart in use to push back lax vaginal side walls when necessary. The side blades 37 are attached to the inner surface of the lower blade 4 by a pin 38 upstanding within the hollow

body of the lower blade 4, the pin 38 being situated on the central longitudinal axis of the lower blade 4 near its proximal end 5. The pin 38 passes through aligned slots 39, one in each side blade as best shown in Figure 9, to attach the side blades 37 to the lower blade 4 in a manner permitting longitudinal axial movement of the side blades 37 with respect to the lower blade 4 and symmetrical pivotal lateral movement of the side blades 37 with respect to each other.

Each side blade 37 comprises a straight proximal portion 40 that is penetrated by a respective longitudinal slot 39 and a convex-curved distal portion 41 that, in use, presses against the vaginal wall (not shown). The proximal portions 40 of the side blades 37 overlap to align their respective slots 39 and hence loosely to accommodate the pin 38 within the aligned slots 39. When so arranged, the distal portions 41 of the side blades 37 lie beside one another in oppositely-curved relation and, at their proximal junction, they embrace a post 42 that projects upwardly from the inner surface of the lower blade 4 on its central longitudinal axis, spaced distally with respect to the pin 38. The post 42 projects upwardly to the extent necessary to match or exceed the combined thickness of the overlapping side blades 37.

In use, squeezing together the forward operating lever 6 and rearward operating lever 7, brings the top edge of the flap 33 carried by the rearward operating lever 7 into contact with the proximal ends 5 of the side blades 37. Figure 8 shows the situation when the flap 33 is about to come into contact with the proximal ends 5 of the side blades 37. With continued squeezing movement as shown in Figure 9, the flap 33 pushes on the proximal ends 5 of the side blades 37 and causes the side blades 37 to move distally with respect to the pin 38, this longitudinal movement being accommodated by relative movement between the pin 38 and the slots 39. In doing so, the proximal junction between the convex-curved distal portions 41 of the side blades 37 is forced against the post 42, which by virtue of the ramp-like shape defined by the inner curved surfaces of the distal portions 41, forces the distal portions 41 apart. This results in the distal ends of the side blades 37 splaying apart about a pivot axis defined by the pin 38 within the slots 39. It will be noted that the proximal ends 5 of the side blades 37 are rounded in plan to minimise friction during their resulting lateral movement against the flap 33.

Eventually, the side blades 37 splay apart to the extent that the distal portions 41 project laterally beyond the periphery of the lower blade 4, as shown in Figure 9, and

thereby begin to bear against the vaginal side walls. So, not only can the invention achieve enlargement of the proximal aperture through a single one-handed action, but also the side blades can be deployed by the same action as and when they are required.

Those skilled in the art will know that the situation addressed by the side blades 37 is encountered quite infrequently, maybe less than one in fifty cases that an average physician in the field would normally encounter. Accordingly, it is desirable that in the normal situation in which the side blades 37 are not required, they stow away within the hollow body of the lower blade 4 in a manner that does not block the physician's visual or physical access, and that selectable means are provided to avoid actuation of the side blades 3 7 unless they are required.

This is the purpose of the aforementioned pivotal mounting of the oblong flap 33 to the rearward operating lever 7. In an alternative mode, the flap 33 can be pivoted about the pivot axis defined by the lugs 34 so that the major portion is below the pivot axis. In this mode, the minor portion of the flap 33 that consequently lies above the pivot axis is too short to engage the proximal ends 5 of the side blades 37, and so does not cause the side blades 37 to splay apart when the operating levers 6, 7 are squeezed together. In this way, the pivotable flap 33 constitutes a selectable drive means that allows the speculum 23 to be used either as a bivalve speculum or as a multi-valve speculum.

As the most advantageous stowed position of the side blades 37 is below the upper periphery of the lower blade 4, provision may be made for the side blades 37 to lift away from the inner surface of the lower blade 4 during the splaying action. For example, the pin 38 should be long enough to accommodate lifting of the straight proximal portions 40 away from the inner surface of the lower blade 4, and the post 42 should be long enough still to engage both of the side blades 37 when so lifted. The actual lifting movement itself could be driven in various ways but most simply by allowing the convex-curved distal portions 41 of the side blades 37 to follow the upwardly-curving cross-section of the lower blade 4 as they splay apart.

It is envisaged that the speculum of this invention will find favour with physicians around the world who seek to combine the simplicity of Cuscoe's speculum with even greater adaptability than is offered by Graves' speculum. The invention provides the only speculum that has a mobile hinge to enlarge the introitus of the vagina, if required, and at the same time to expose the vaginal canal by one simple

movement of squeezing together a pair of operating levers. The speculum will be invaluable in labour wards for inspection of vaginal and or cervical tears after delivery, and more generally in colposcopy and gynaecology clinics and gynaecology wards and theatres where sometimes bivalve specula are not adequate.

Many variations are possible within the inventive concept. For example, the shape, size and material of the speculum can be selected to suit particular circumstances. Also, whilst there is not much scope, or indeed any need, to change the basic size or shape of a gynaecological speculum, or at least its blades, it should be noted that the invention in its broadest sense is not limited solely to gynaecological specula. Nor is the invention limited to the addition of supplementary blades to the basic upper and lower blades of a bivalve speculum.

Indeed, many other variations are possible without departing from the inventive concept defined herein. Accordingly, reference should be made to the claims and other conceptual statements herein rather than to the foregoing specific description as indicating the scope of the invention.

The present invention comprises additional embodiments described below with reference to Figures 10-18. A first embodiment of those Figures 10 and 11 comprise an alternate form of interaction between the threaded rod 10 and the operating lever 7 of Figures 1-9. Another embodiment of the side aperture support means of Figures 8 and 9 are shown in Figures 12-18.

In order that the alternate embodiments of the present invention can be more readily understood, reference will now be made, by way of example only, to the accompanying further drawings in which:

Figures 10 and 11 are side and rear views of an adapted Cuscoe speculum where a side slot on the top blade means permits upward movement securable into one of two positions with threaded rod connection with the operating lever.

Figures 12 and 14 are substantially identical side and rear views as in Figures 10 and 11 except that one of two sidewall support blades with movement means is shown integrated into the speculum of Figures 10 and 11.

Figure 13 is a top view of a single sidewall support blade integral with a movement means connection plate.

Figures 15 / 16 and 17 / 18 are respectively side and top views of the device of Figures 12 and 14 without a top blade assembly so that operation of the sidewall support blades may be illustrated.

Figures 10 and 11 show an embodiment where the threaded rod 209 and truncated cylinder nut 210 interact with lever 107 to provide a two location device for raising the top blade assembly 100 above the bottom blade assembly 200 via the relative motion along slots 105 with connecting rivet 204 having a connecting shaft 203. Assembly 100 comprises a top blade insertion section 101 with a flared viewing transition 102, where assembly 200 similarly comprises a bottom blade insertion section 201 and flared viewing section 202. Portions of section 102 extend to side plates 104, each having a slot 105, within which are defined a slideable shaft 203 of rivet 204. Plates 104 extend and form hinge connection 106 with lever 107. Connection 106 is well known in the Cuscoe speculum art as providing means for folding lever 107 only in direction 108 for compact storage of lever 107.

Assembly 200 comprises a welded handle connection 205 at the bottom of section 202, the connection 205 forming a hinge connection 206 with lower handle section 207, which similarly to lever 107, hingedly folds toward a bottom outside surface of section 201. Lower handle section 207 further comprises secure and rigid

connection 208 (as in Figure 10) or hinged connection 208' (as in Figure 12), such that rod 209 may be held, respectively, rigidly rearward of section 207 or may rotate about a hinge at connection 208' as in Figure 12.

It will be appreciated with the above disclosure that assembly 100 may be moved upwardly in direction 211 with respect to a stationary assembly 200 whereby rivets 204 connecting extensions of section 202 with slots 105 substantially maintain in a vertical plane midline axes of sections 101 and 201, i.e., the top and bottom blades can be separated while so that the top blade can be rotated about the axis formed by the rivets 204 without skewing the top blade away from the bottom blade. Lever 207 further comprises a bottom cutout 112 large enough to allow passage of nut 210 therethrough. Slots 109 and 110 are not large enough to permit that passage and define, respectively, mid-height and most extended height of assembly 100 above assembly 200. The movement of the assemblies 100 and 200 apart and together via the interaction of the rivets 204 and slots 105 are stopped at certain distances due to the abutting of rod 209 with the top U-shaped ends of slots 109 and 110. The compression during use of sections 101 and 201 toward one another causes the just described rod 209 abutting to the top ends of either slot 109 or 110. Figure 11 is shown with assembly 200', which is assembly 200 with the lower handle removed for clearer viewing – it is understood that such lower handle is to be included in the invention device as critical to insertion, manipulation and removal functions.

With respect to the embodiments of Figures 12-18, the following description applies. Figures 12-18 are shown with reference to assemblies 100 and 200 as substantially shown in Figures 10 and 11 without complete reference to the numbered aspects thereto, it being understood that the device of Figures 10 and 11 are slightly modified as described below to accommodate the sidewall support blade means of this embodiment of Figures 12-18.

In Figures 12-18, sidewall support blade means 300 comprise a sidewall support blade 301 connected at transition 307 to plate sections 302, 303 and 304, the plate sections respectively having connection, slot 305 defining and rivet hole 306 defining functions. Figure 13 shows a substantially planar plate sections 302-304, although as seen in Figure 14 as to the rear view of the blade 301 and sections 302-304 lying within the closed cavity of sections 101and 201, the blade 301 and sections 302-304 are intended to be adapted to achieve the objects of the embodiment with curvature or cutouts such that sections 101 and 201 can open, close and be moved apart as in

the embodiments of Figures 10 and 11 without interference.

The present embodiment adds only a few pieces added to the device of Figures 10 and 11, whereby very substantial vaginal sidewall support is obtained. The additional pieces are two blade pieces (having a blade 301 and sections 302-304 and a mirror image blade 401 and sections 402-404), a rotatable handle (with U-shaped piece 310 with ends 311 rotatably connected with rivets 204, and further having a depressible handle 309 connected at section 308) and two rivets (rivets 312 and 313 located and loosely fitting in respectively piece 310 and in a floor of section 202. The very surprising interaction of these few additional and easily fabricated and installed pieces is to permit movement of sidewall support blades 301 and 401 from the retracted positions seen in Figures 12, 14, 15 and 16 into the sidewall support positions seen in Figures 17 and 18. This very effective sidewall support is accomplished with no more than thumb or finger pressure in direction 314 of handle 309.

The action of this embodiment is achieved by the following interaction. For clarity, Figures 12, 13, 15 and 17 show only a right blade piece comprising the blade 301 and sections 302-304. It is understood from Figures 15 and 16 that the mirror image blade piece 400 is intended to be used in addition to that right blade piece of Figures 12, 13, 15 and 17 to achieve an object of the invention. However, a right blade piece or blade piece 400 may be used less preferably alone whereby the same sidewall support function may be obtained only for a single vaginal sidewall at the aperture formed at the opening of sections 101 and 201 with respect to each other (as shown in Figure 17 with assembly 200 shown in broken lines). Rivets 312 and 313 have shafts slightly longer than the thicknesses of the holes they pass through. Rivet 312 is intended to have a shaft that will pass connectively through a hole in piece 310, hole 306 of the right hand blade piece, and corresponding hole 406 (not shown) in blade piece 400. In addition, rivet 313 is intended to have a shaft that will pass connectively through a hole in the floor of section 202, slot 305 of the right hand blade piece and corresponding slot 405 in blade piece 400. The length of the shafts of rivets 312 and 313 are lengthened to accommodate the levering action taking place as the blade pieces are forced from a retracted (Figures 15 and 16) to and expanded position (Figures 17 and 18). Direction 314 motion of piece 310 (via depression of handle 309) presses the connected blade pieces forward such that the blade piece moves at an acute angle to the longitudinal axis of section 201 due to

the restriction of that motion to the direction of slots 305 or 405. It is intended that the an outer edge of the blade piece may slidingly contact a portion of the inside curvature of section 201 as shown in the broken lines zone 315 of Figure 12.

For example, in Figure 15, the outer edges of the blade pieces may contact that inner curvature at points 315A and 415A. In pressing the blade pieces toward the sides of inside curvature of the section 201 via the interaction with slots 305 and 405, the outside edge of the blade pieces are thereby slidingly contact pushed UP the sides of the inside curvature such that the sidewall support blades are delivered into an aperture formed by the opened sections 101 and 201. In an expanded position for the blade pieces as in Figures 17 and 18, the blade pieces supportively contact a top side / edge of section 201 at points 315B and 415B. This interaction of the outside edges of the blade pieces with the inside curvature of the bottom blade is critical to devising an instrument with minimal additional parts that moves sidewall support blades to a desired expanded position. The movement of the blade pieces close to the inside curvature of the bottom blade minimizes line of sight blockage for the practitioner using the invention device with the blade pieces in the retracted position.

The sidewall support blades of Figures 12-18 are shown in a generalized maximum in terms of lateral sidewall support surface that will be encloseable within the cavity formed by closed top and bottom blades of the Cuscoe type speculum. It is within the scope of the present invention that the sidewall support blades be smaller, narrower, shorter (lengthwise) or simple rods. The object of this embodiment is that sidewall support is delivered to the aperture formed by the opening of the opened top and bottom blades of the Cuscoe type or other speculum.

CLAIMS

1. A speculum comprising co-operating blades defining a proximal aperture, each blade being associated with a respective operating lever such that relative movement of the operating levers causes relative movement of the blades, wherein a mechanism operable by said relative movement of the operating levers causes the proximal aperture to vary.

2. The speculum of Claim 1, wherein the mechanism includes a ramp along which a ramp follower can move during said relative movement of the operating levers, relative movement of the ramp follower along the ramp causing said variation of the proximal aperture.

3. The speculum of Claim 2, wherein the ramp follower slides along the ramp.

4. The speculum of Claim 2 or Claim 3, wherein the ramp follower is shaped to define a line of contact with the ramp, said line of contact being transverse to the direction of movement along the ramp.

5. The speculum of Claim 4, wherein the ramp follower is cylindrically curved about an axis transverse to the direction of movement along the ramp.

6. The speculum of any of Claims 2 to 5, wherein a first locking member is movable with respect to the ramp to prevent relative movement of the operating levers as the blades are subject to inward pressure in use.

7. The speculum of any of Claims 2 to 6, wherein the ramp is attached to or part of one of said operating levers and the ramp follower is attached to or part of the other of said operating levers.

8. The speculum of Claim 7, wherein the ramp is movably attached to an operating lever.

9. The speculum of Claim 8, wherein the ramp is attached to the associated operating lever by a pivot.

10. The speculum of Claim 8 or Claim 9, wherein the ramp is lockable to prevent movement relative to the operating lever to which it is attached.

11. The speculum of Claim 10, wherein a second locking member is movable with respect to the ramp to lock the ramp relative to the operating lever.

12. The speculum of Claim 11, wherein the ramp is defined by a rod along which the first and/or second locking members can be moved.

13. The speculum of Claim 12, wherein the rod is threaded and the first and second locking members are nuts in threaded engagement with the rod.

14. The speculum of Claim 13, wherein a bearing surface of the rod is non-threaded.

15. The speculum of any preceding Claim, wherein the blades are joined for co-operating relative movement by a floating hinge or pivot.

16. The speculum of any preceding Claim, wherein the operating levers are obtusely angled in a proximal direction with reference to the blades.

17. The speculum of any preceding Claim, wherein the operating levers are disposed one behind another as forward and rearward operating levers.

18. The speculum of Claim 17 when appendant to Claim 16, wherein the rearward operating lever is oriented at a greater obtuse angle to the blades than the forward operating lever.

19. The speculum of any preceding Claim, wherein the blades are upper and lower blades that co-operate when closed to define a hollow body and supplementary blade means are situated within the body, the supplementary blade means comprising side blades that open laterally from within the body when the upper and lower blades are opened.

20. The speculum of Claim 19, wherein drive means associated with at least one of the operating levers actuate the supplementary blade means upon relative movement of the operating levers.

21. The speculum of Claim 20, wherein the drive means are selectable to prevent relative movement of the operating levers actuating the supplementary blade means.

22. The speculum of Claim 20 or Claim 21, wherein the drive means comprises a drive member attached to or part of an operating lever that bears against proximal ends of the side blades when the upper and lower blades are opened and causes the side blades to move distally against an acting member that causes the side blades to splay apart.

23. The speculum of any of Claims 19 to 22, wherein the side blades are movably attached to the lower blade by a floating mount that permits the side blades to lift out of the interior of the lower blade as they splay apart.

24. A speculum comprising first and second blades that co-operate to define a proximal aperture, the first blade being associated with a first operating lever and the second blade being associated with a second operating lever that is connected by a pivot to the first operating lever such that relative pivotal movement of the operating levers towards one another causes the blades to move apart, wherein the pivot is a

floating pivot permitting relative translational movement between the operating levers to vary the proximal aperture and wherein the operating levers are also connected by a ramp associated with the first operating lever and a ramp follower associated with the second operating lever, the ramp being opposed to the pivot so that the pivotally-connected operating levers and the ramp define the three sides of a triangle, the arrangement being such that during relative pivotal movement of the operating levers towards one another, the ramp follower moves up the ramp towards the pivot, this movement of the ramp follower up the ramp causing translational movement at the floating pivot of the second operating lever, which translational movement widens the proximal aperture.

25. The speculum of Claim 24, wherein the ramp or the ramp follower can be adjusted · so as not to come into contact with one another during Said relative pivotal movement of the operating levers towards one another.

26. The speculum of Claim 24 or Claim 25, wherein the ramp is pivotably movable in relation to the operating lever with which it is associated, and locking means are provided to hold the ramp in fixed angular relation to that operating lever during said relative pivotal movement of the operating levers towards one another.

27. A speculum substantially as hereinbefore described with reference to or as illustrated in any of Figures 5 to 9 of the accompanying drawings.

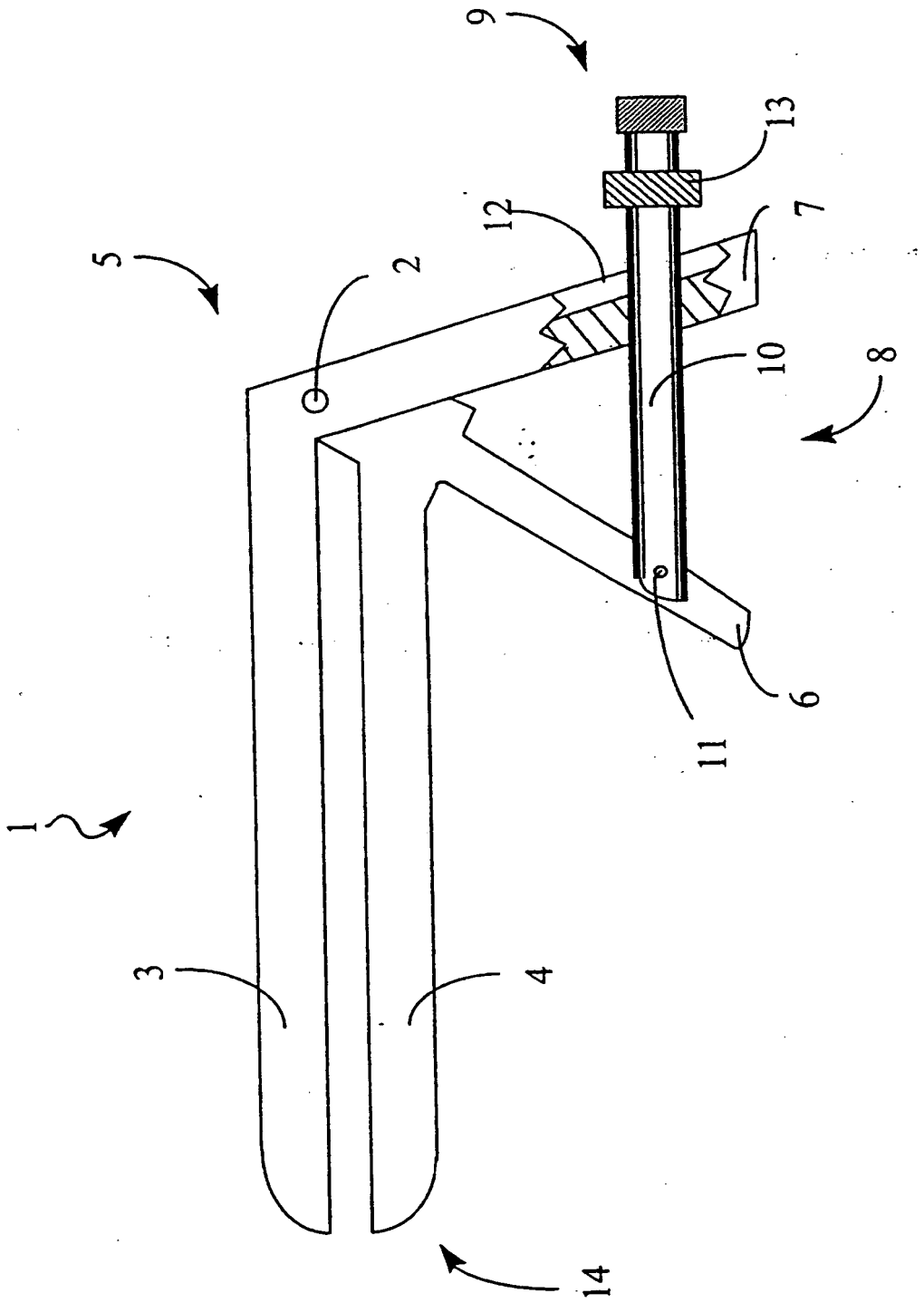
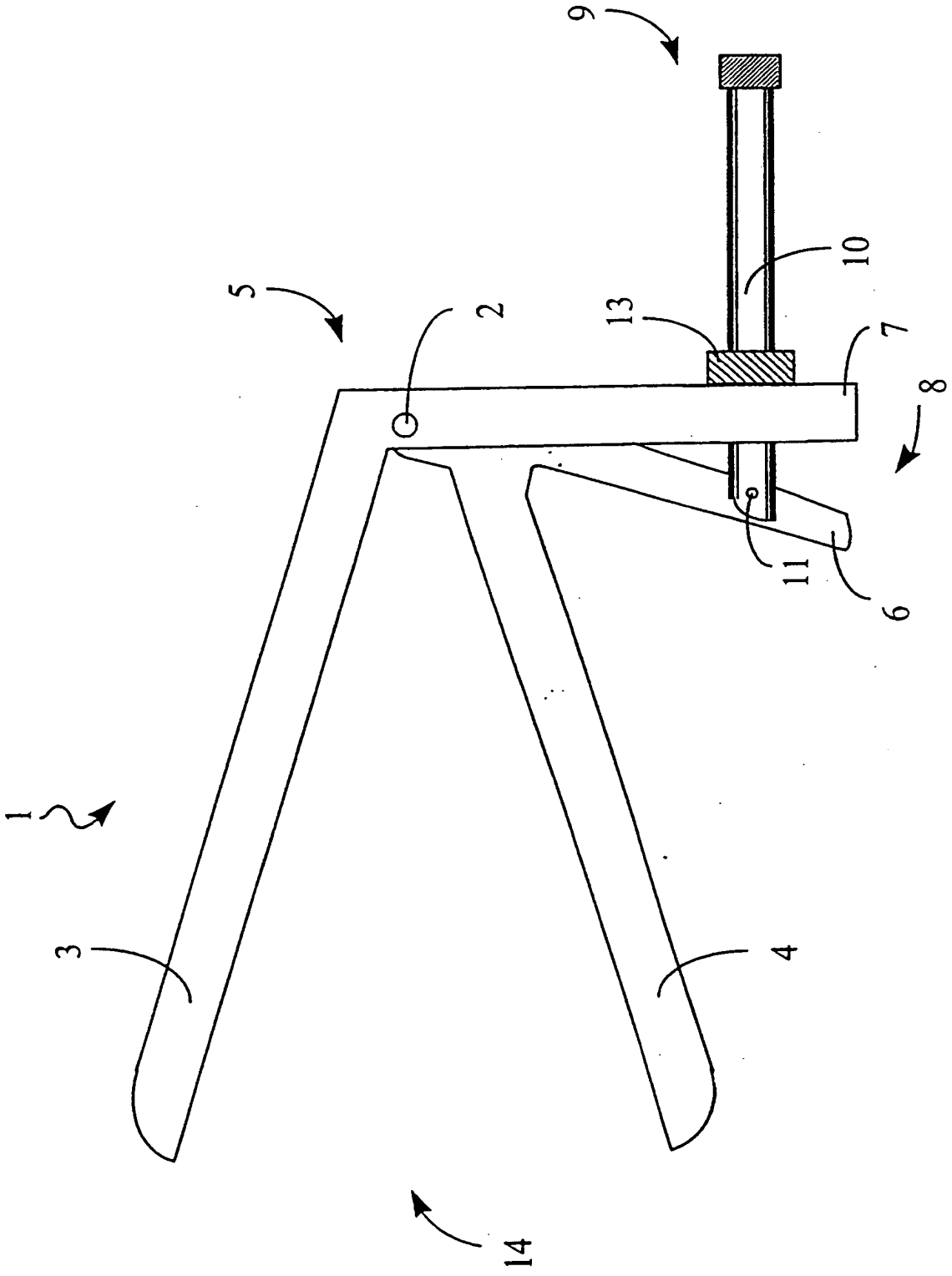


Figure 1

Figure 2



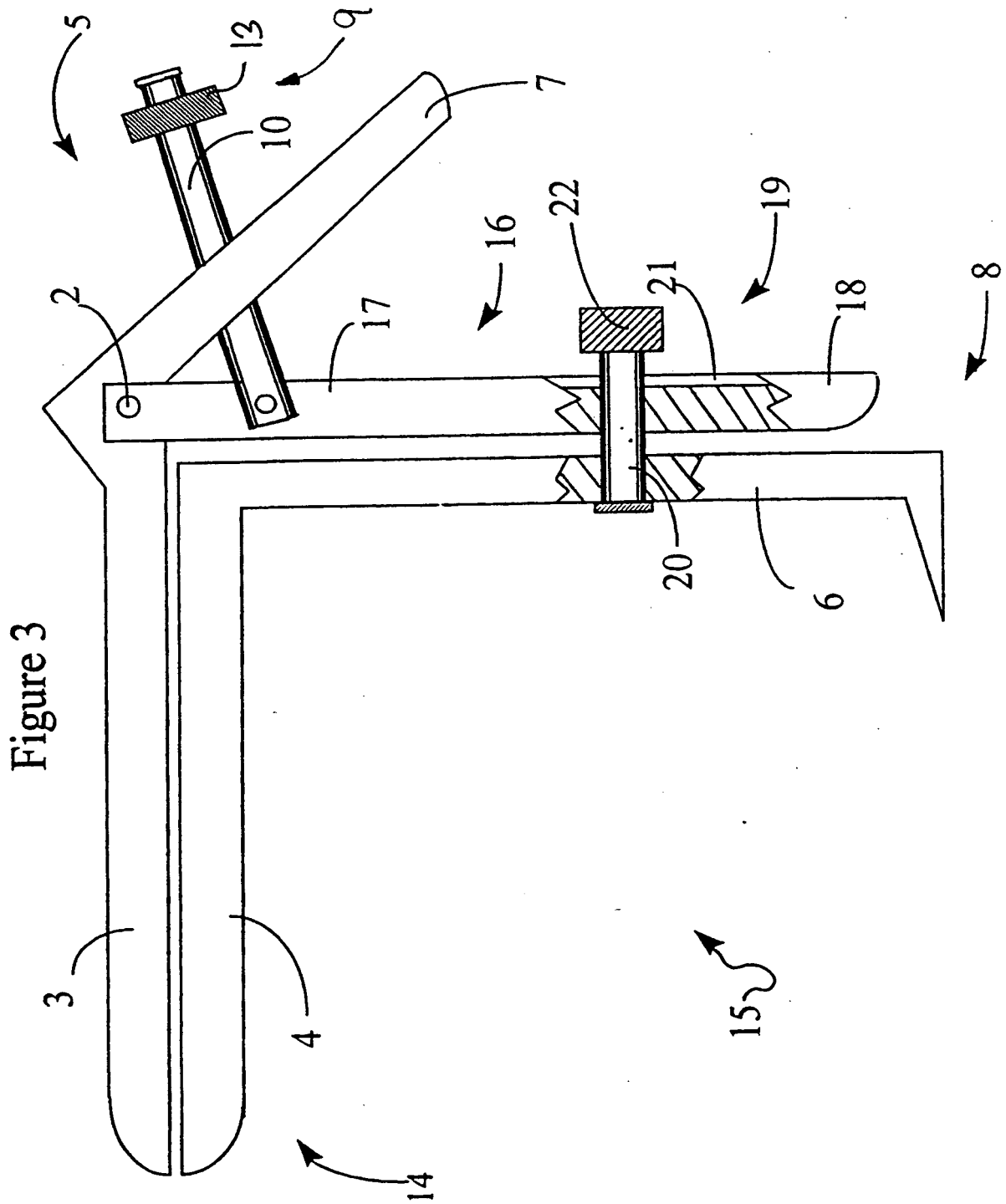


Figure 3

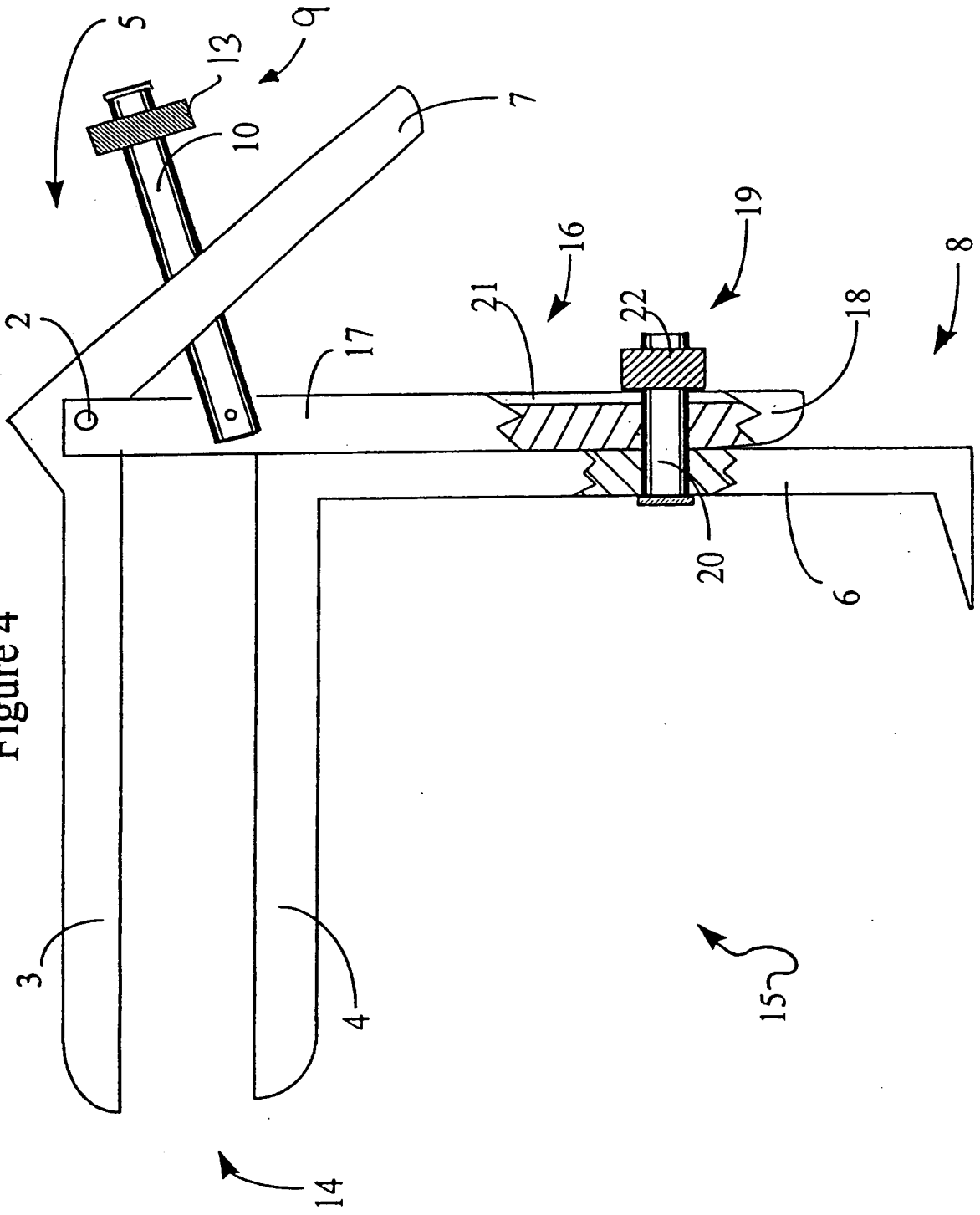


Figure 4

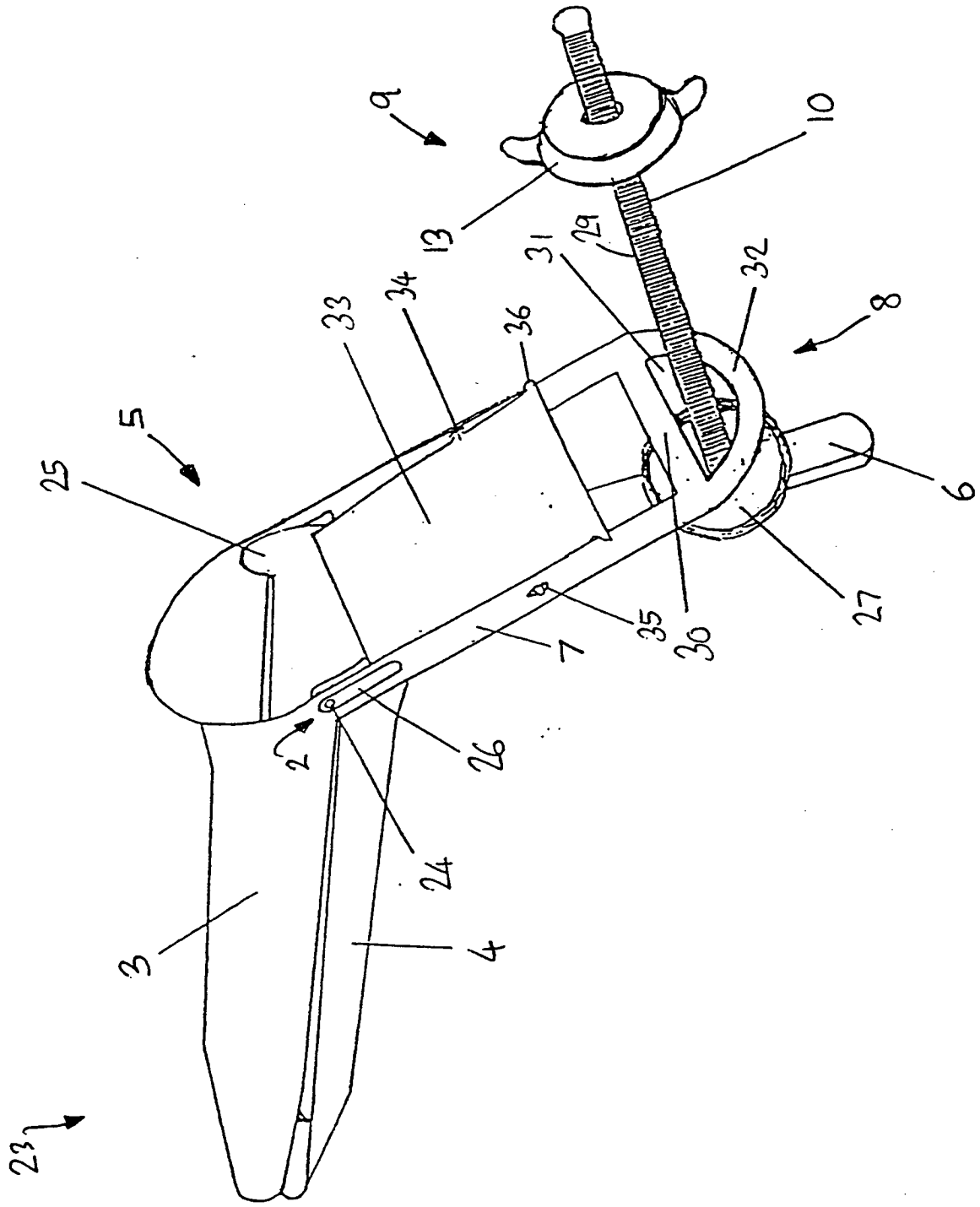


Figure 5

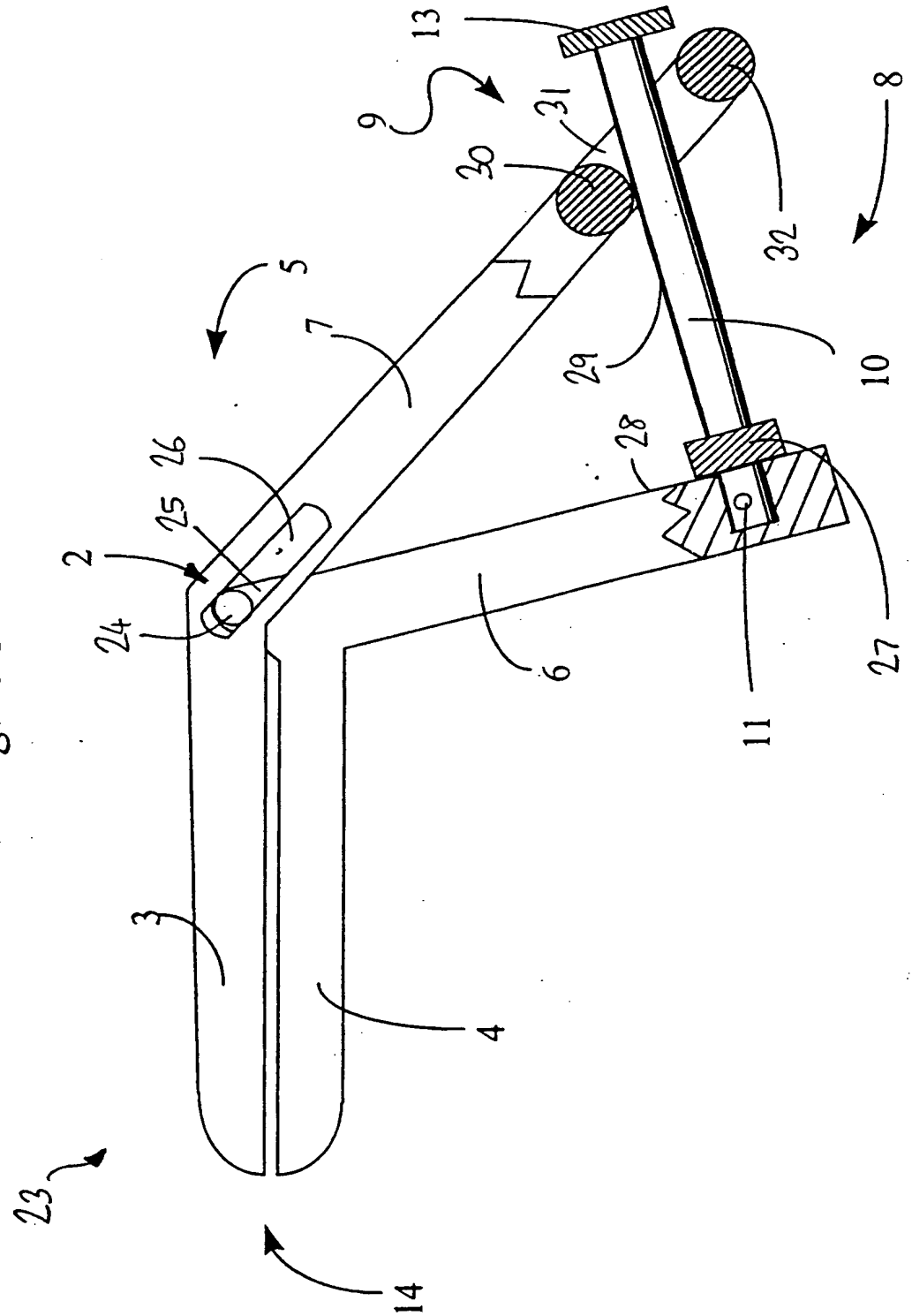


Figure 6

Figure 7

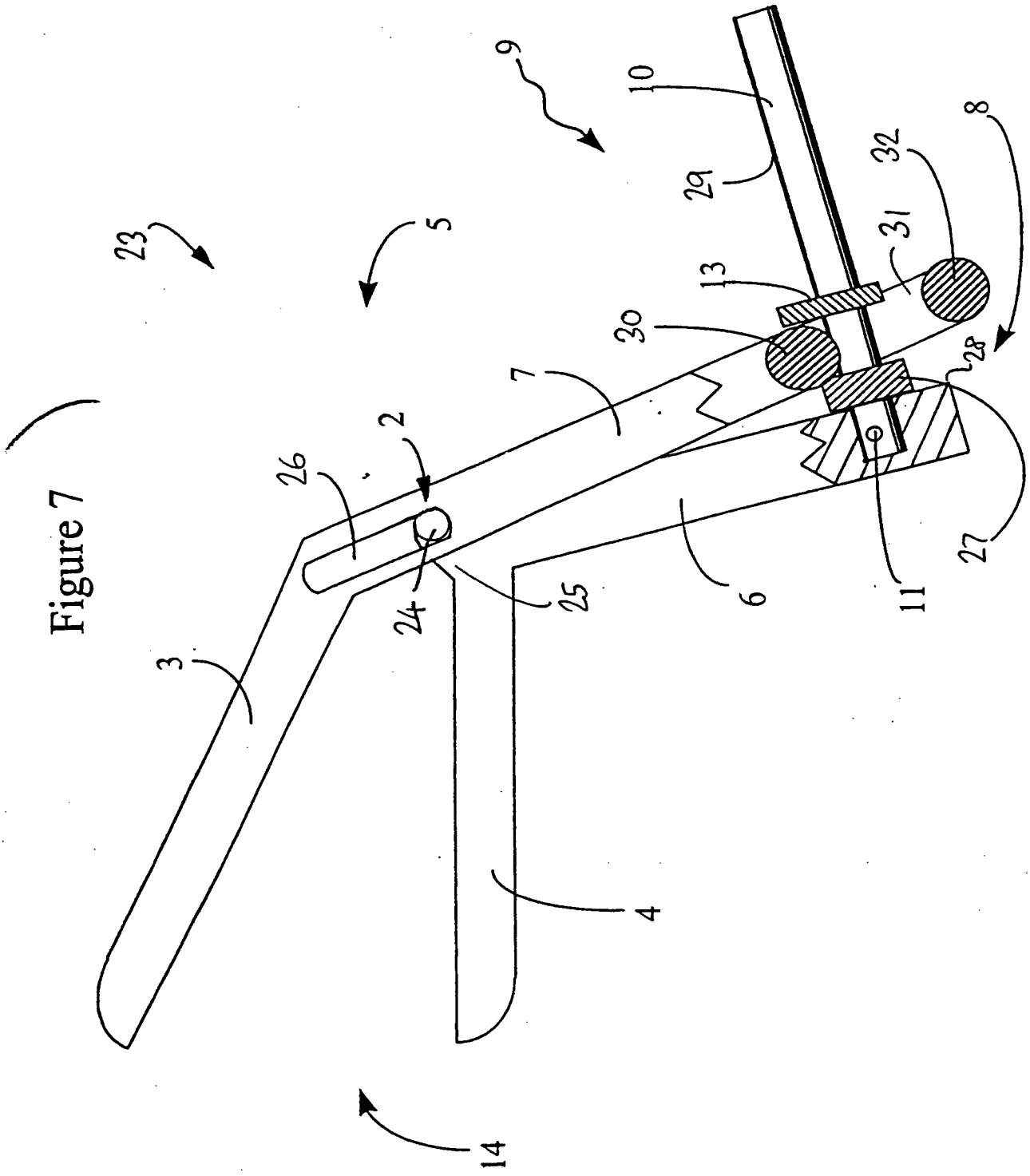


Figure 8

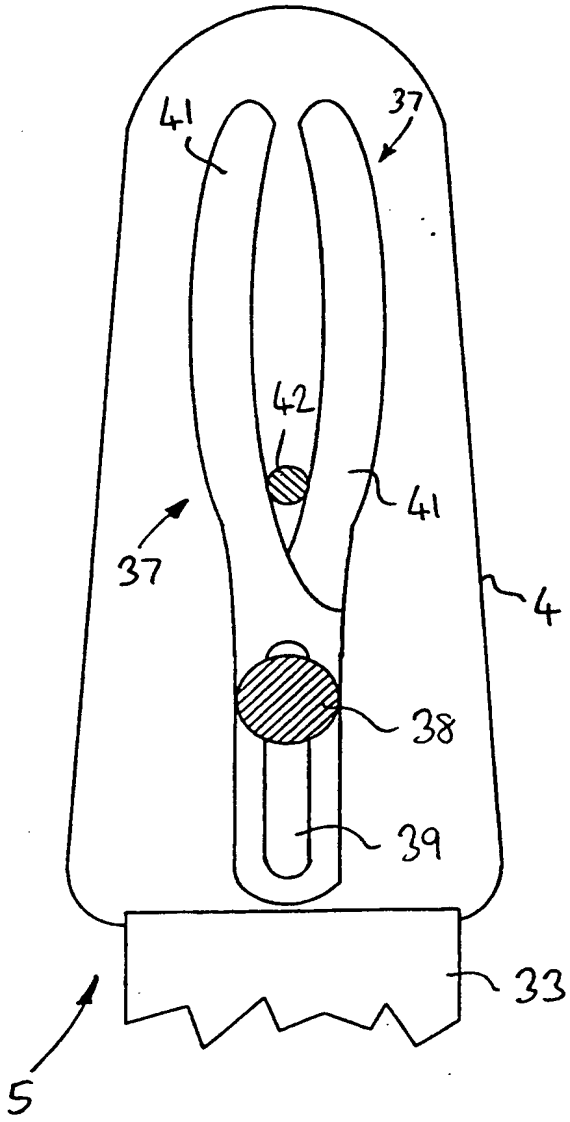
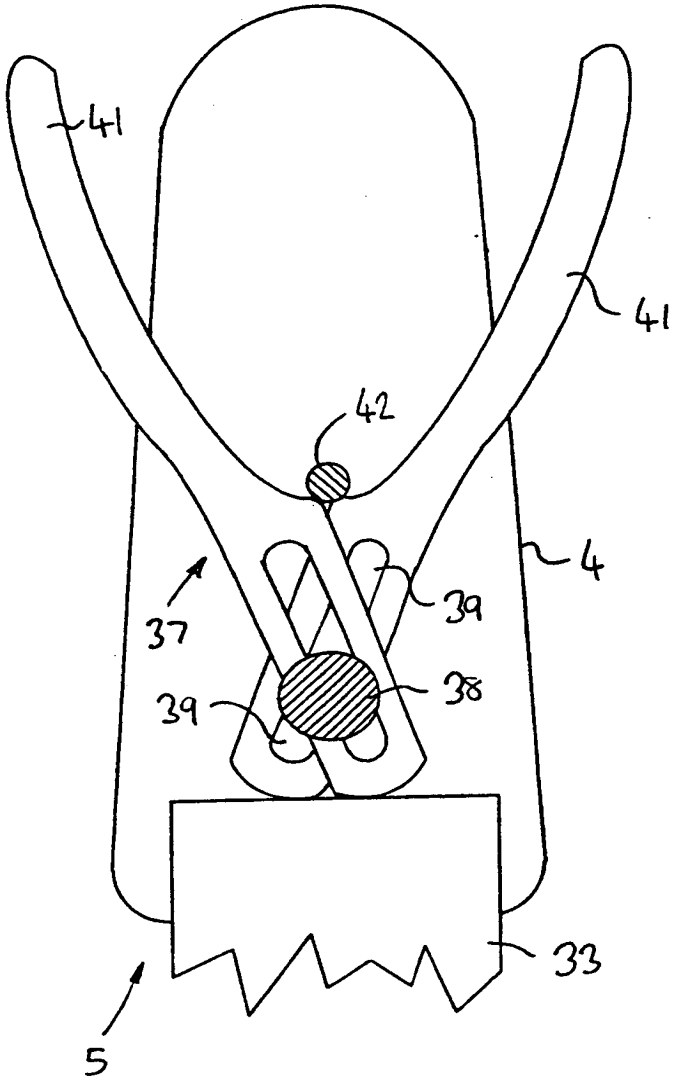


Figure 9



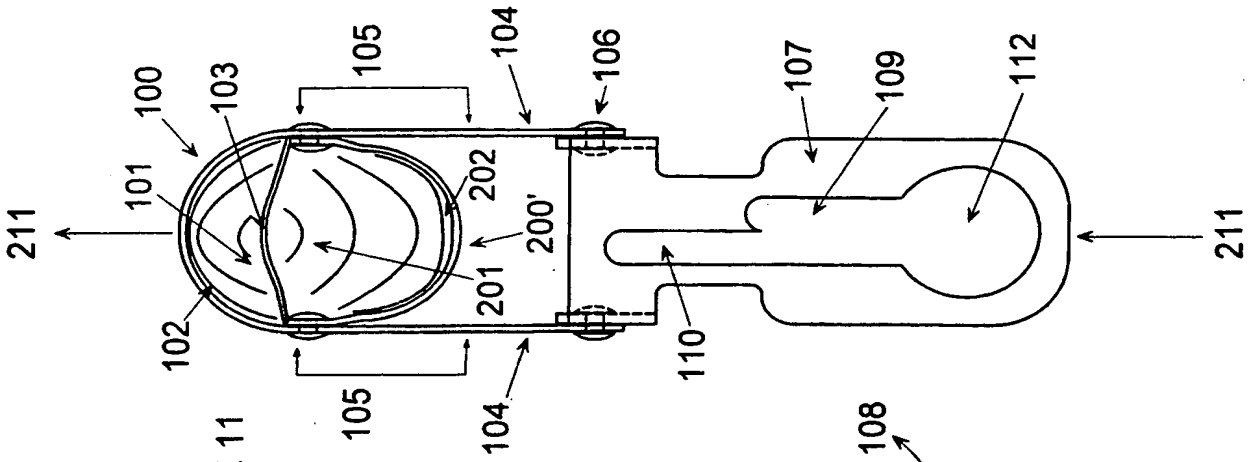


FIGURE 11

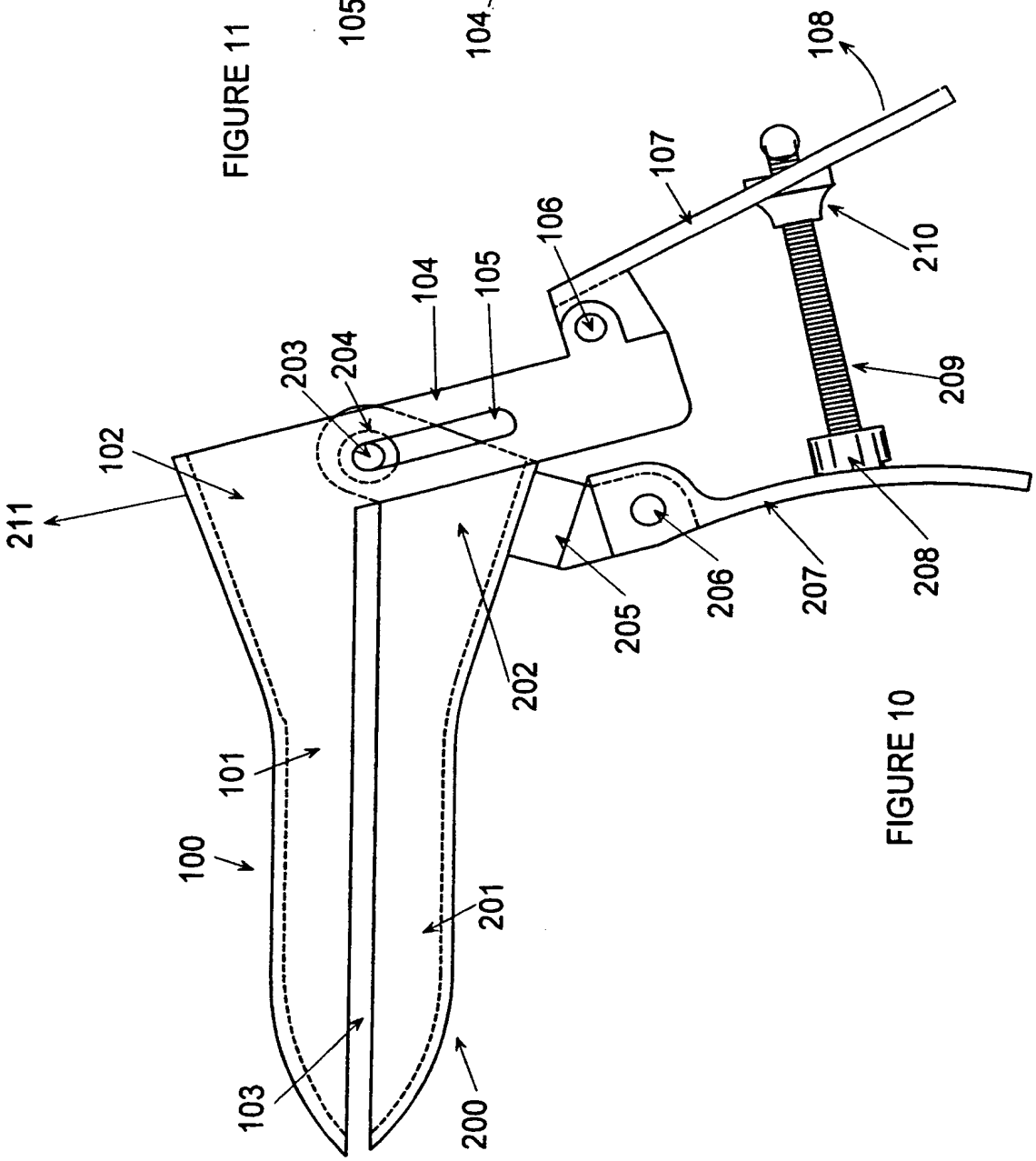


FIGURE 10

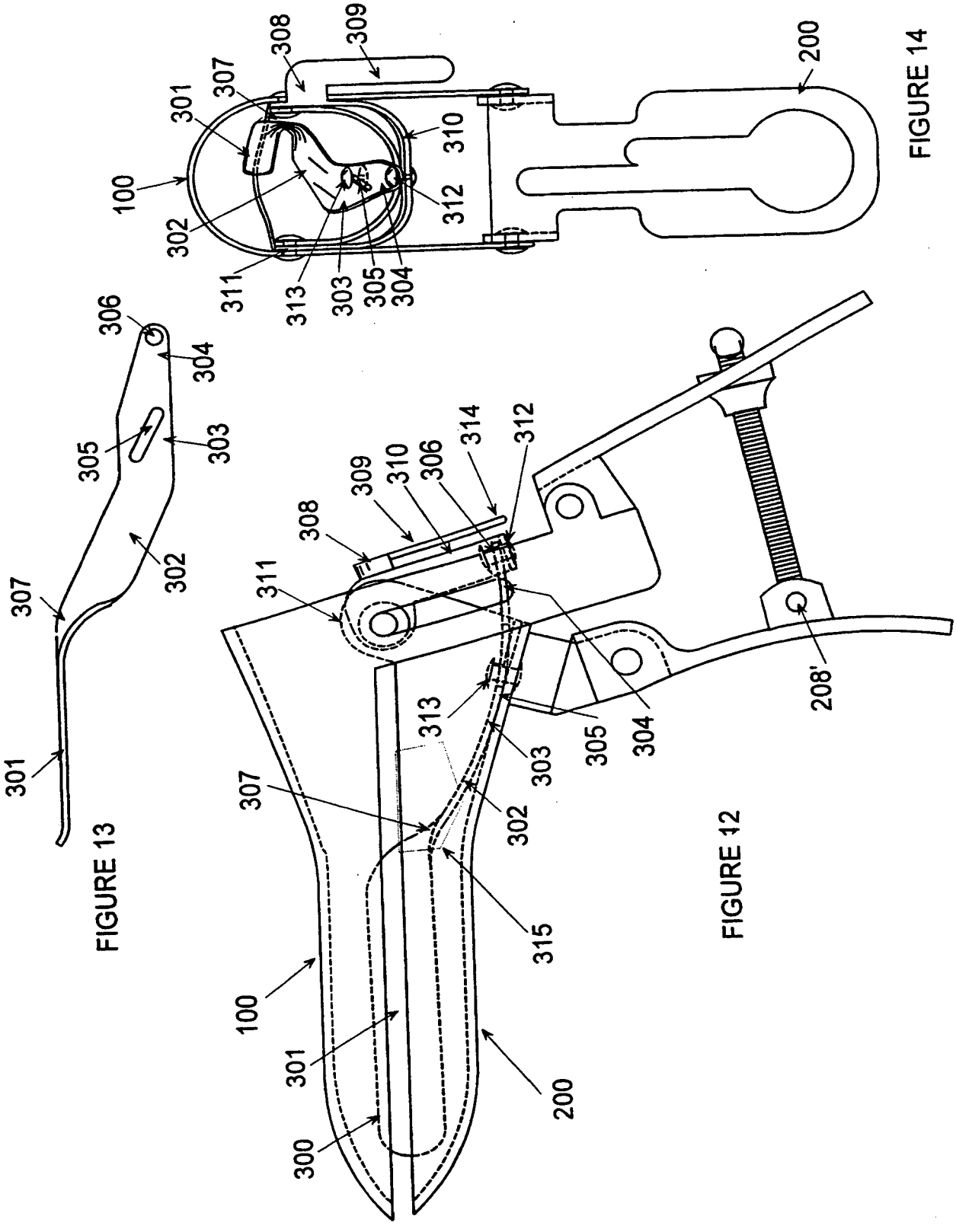
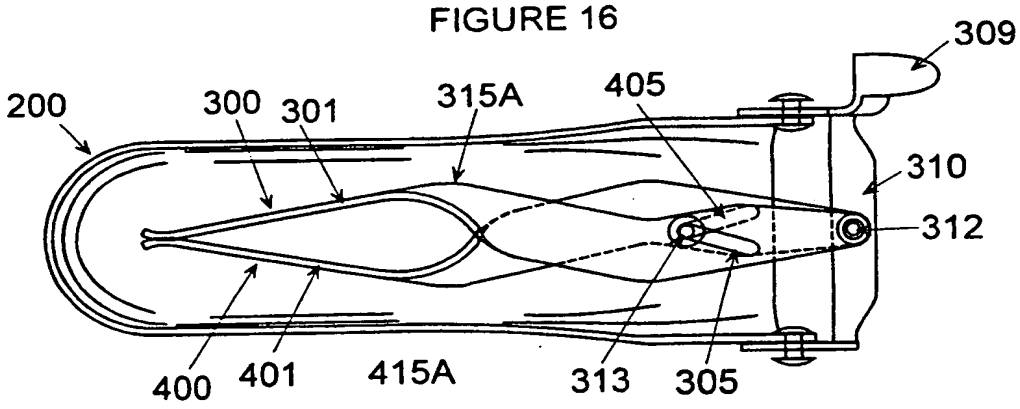


FIGURE 12

FIGURE 13

FIGURE 14

FIGURE 16



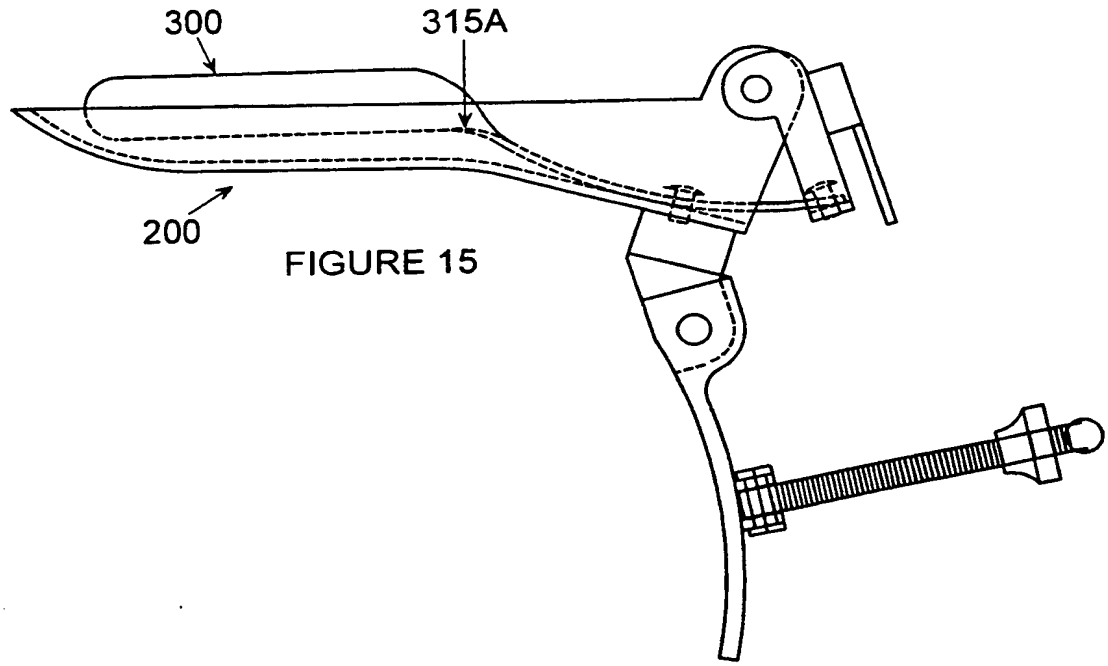


FIGURE 15

FIGURE 18

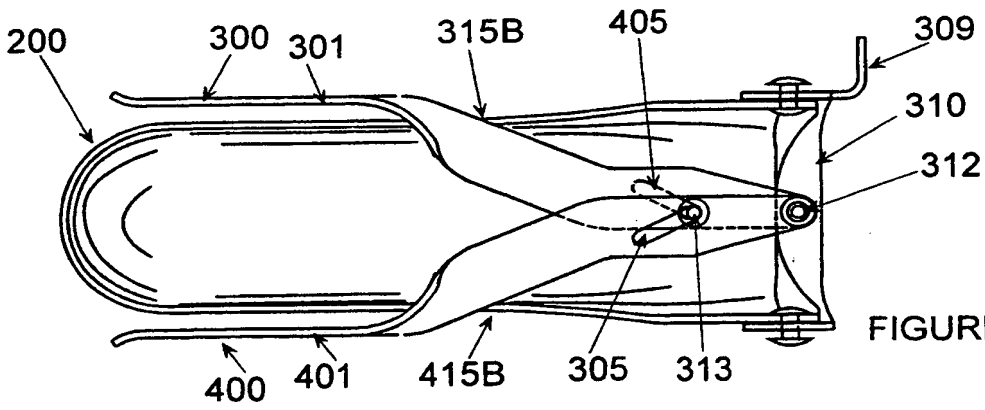


FIGURE 18

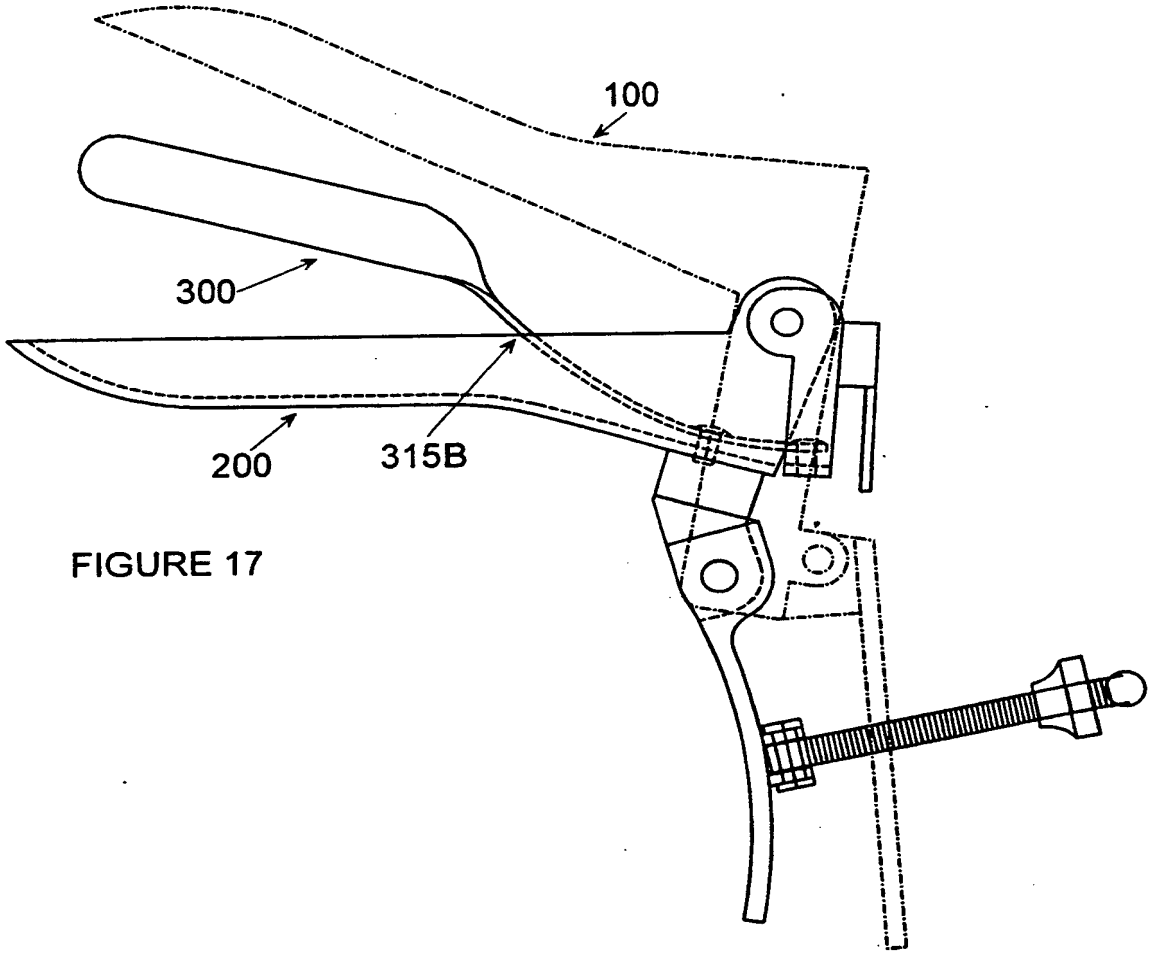


FIGURE 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/13045

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61B 1/32
US CL :600/222
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/196, 219, 220, 222

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 187,625 A (HARDING) 20 February 1877, entire document.	1-5, 24-26
X	US 3,890,961 A (MOORE) 24 June 1975, entire document.	1-4, 24-26
X	US 325,647 A (BAILY) 08 September 1885, entire document.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 09 SEPTEMBER 2000	Date of mailing of the international search report 13 OCT 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JEFFREY A. SMITH Telephone No. (703) 308-3588

Form PCT/ISA/210 (second sheet) (July 1998) ★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/13045

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 27
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

claim 27 sets forth an "omnibus-type" claim of such breadth that no meaningful search could be carried out. Moreover, claim 27 fails to satisfy PCT Rule 6 in that it does not set forth those technical features of the invention which are necessary for the definition of the claimed subject matter.

3. ☒ Claims Nos.: 6-23
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.